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**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Docket Number (Optional)

ALG10220P00050US

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on February 18, 2010

Signature

Typed or printed name Corinne Byk

Application Number

10/562,387

Filed

May 11, 2006

First Named Inventor

Christiaan Michiel Ten Bruggenkate

Art Unit

3732

Examiner

Heidi Marie Eide

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐

applicant/inventor.

☐

assignee of record of the entire interest.

See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.  
(Form PTO/SB/96)☒

attorney or agent of record.

Registration number 32,273☐

attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34 \_\_\_\_\_

Signature

F. William McLaughlin

Typed or printed name

(312) 876-2120

Telephone number

February 18, 2010

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below\*.

☒\*Total of 2 forms are submitted.

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**STATEMENT FOR PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Claims 1, 3-6 and 8-17 are pending in the application and are rejected. The rejections of record are not proper and are without basis and are based upon a clear legal or factual deficiency. The deficiencies comprise ignoring express claim limitations and relying on an inaccurate interpretation of the principal reference.

In accordance with the invention, an implant device uses thread parts which serve as retention elements having a shallow slope at the apical (insertion) side and a steep or more rectangular shape on the cervical side. The retention elements function similar to shark teeth. During surgery, the retention elements allow the implant to enter the bony preparation and then hook onto the surrounding bone. This latter feature prevents the implant from being removed by pulling the implant out of the bone tissue.

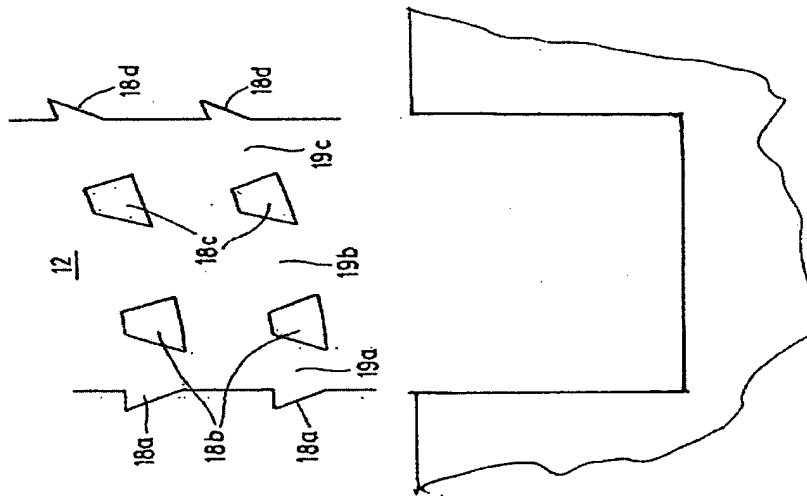
The claims are all rejected based primarily on Mena US 2002/0102518. Particularly, claims 1, 3 and 9 are rejected as anticipated, while claims 4-6, 8 and 10-17 are rejected as obvious over Mena in combination with other references. The application includes only one independent claim and this request will focus specifically on the deficiencies of Mena with respect to independent claim 1.

Independent claim 1 specifies, in pertinent part, an intra-osseous implant for placement in bone of a human or animal body comprising a part having an apical side and a cervical side. The part is provided on its circumferential surface with an interrupted screw thread. Multiple interrupted screw thread parts serve as retention elements allowing the placement of the implant in the longitudinal direction into the bone tissue but preventing the removal of the implant in the opposite longitudinal direction out of the bone. The retention elements are provided with a profile exhibiting a shallow slope toward the apical side and a steep slope on the cervical side.

Mena does not disclose or suggest retention elements allowing placement of an implant in a longitudinal direction into the bone tissue. Nor does it disclose preventing removal of the implant in the opposite longitudinal direction out of the bone. More particularly, Mena does not

disclose that thread parts are provided with a profile exhibiting a shallow slope toward the apical side and a steep slope on the cervical side.

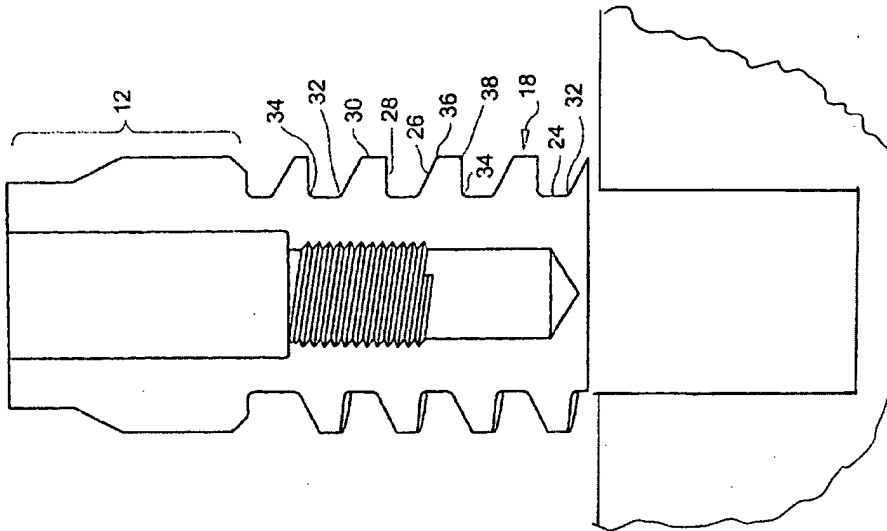
Below is an image showing Fig. 3b of the present application with an added insertion opening in bone tissue to the right. The cervical side is to the left and the apical side to the right.



**Applicant Fig. 3(b) with bone**

It is readily apparent that the retention elements 18a, b, c and d, which exhibit the claimed shallow slope toward the apical side (the right side) and a steep slope on the cervical side, allow the placement of the implant in a longitudinal direction (from left to right) but prevent the removal of the implant in the opposite longitudinal direction out of the bone (from right to left). Particularly, the retention elements hook into the side walls of the preparation opening to prevent removal in the longitudinal direction (from right to left).

Below is an image showing Fig. 3 of Mena with an added insertion opening in bone tissue to the right. Again, the cervical side is to the left and the apical side to the right.



**Mena Fig. 3 with bone**

It is apparent that with the thread portions 18 of Mena longitudinal insertion is not possible. Moreover, the thread profile is opposite. The Mena threads have a steep slope on the apical side (the right side) which would render it difficult, if not impossible, to allow placement into the bone tissue in a longitudinal direction. In fact, the implant would be more readily removed due to the shallower slope toward the cervical side. Thus, contrary to the statement made in the action, Mena's implant is not capable of functioning as claimed.

The Examiner included an Appendix comprising Fig. 1 of Mena with legends added to identify the thread portion facing the cervical side as a steep slope and the thread portion facing the apical side as a shallow slope. The action included no explanation justifying this assignment of labels. Indeed, the labels are contrary to what is shown above wherein the face of the thread facing the cervical side is clearly shallower than the face of the thread facing the apical side.

Claim 1 of the present application specifies that the multiple screw thread parts are provided with a profile exhibiting a shallow slope toward the apical side and a steep slope on the cervical side. This is represented by the two faces of the thread portions shown above in cross

section. Mena, on the other hand, includes threads having three surfaces. These surfaces comprise an upper face 26 facing the cervical end, a lower face 28 facing the apical end, and a side face 30 which is substantially parallel to the outer face 24. This structure is intended to prevent the device from shearing. Moreover, the lower face is described as being almost perpendicular to the side face. Such a relationship does not comprise a shallow slope. These differences are due to the manner of implantation. Mena's implant is intended to be **threaded** into the bone, rather than being inserted longitudinally. If the device were to be inserted longitudinally, then the diameter of the preparation hole would need to be identical to the outer diameter of the side face 30. Otherwise, it would be impossible to tap the implant part into the preparation hole. Using a wider opening would render the structure inoperable as it could be simply removed. The implant would not anchor itself into the bone tissue. Moreover, the implant device in Mena cannot be tapped inside a bone preparation due to its thread profile, as shown. The bone preparation hole must be wide enough so that the lower face 28 does not catch the bone tissue if it is pushed in. Thus, it is readily apparent that the implant can only be properly placed inside a bone preparation hole by screwing it in, as specifically taught by Mena.

The action effectively ignores the claim limitation that the thread parts serve as retention elements allowing placement of the implant in the longitudinal direction but preventing removal of the implant in the opposite longitudinal direction of the bone. Particularly, the action states that this is an intended use. Applicant disagrees. This limitation is describing a structural characteristic of the thread parts. This limitation should be considered along with the related limitation that the shallow slope toward the apical side allows the placement of the implant in the longitudinal direction while the steep slope on the cervical side prevents removal of the implant in the opposite longitudinal direction out of the bone so that the thread parts structurally are retention elements. Contrary to the statements made in the action, Mena is **not capable** of performing in this manner.

With the profile of the retention elements in accordance with the invention, the bone preparation fits the diameter and circumference of the implant root core, as shown above. The

retention elements dig into the surrounding bone during entering, as if it was a self-cutting thread, but in the longitudinal direction instead of a rotational direction. Thereafter, because of the retention feature, the implant can only be removed by unscrewing the implant, thus creating a rotational thread design in the bone tissue surrounding the implant core.

The Mena reference clearly shows a thread profile **opposite** to the profile of the threads claimed herein. Insertion with a mallet technique is only possible if the bone preparation is about as wide in diameter as the outer diameter of the thread of the implant. As a result, the screw thread parts would **not** dig into the bone tissue when entering in a longitudinal direction. This would preclude any thread portion from anchoring into the surrounding bone. Moreover, with such an enlarged opening the thread profile of Mena would more readily allow removal in the longitudinal direction due to the shallower slope facing the cervical side. There is no retention. In any event, Mena does not disclose any such implantation as Mena clearly states that the implant is designed to be threaded into a smaller opening, as shown above.

Because Mena does not disclose each and every element of claim 1, arranged as in the claim, there is no anticipation and the rejection is improper. Nor does Mena suggest a structure as defined by claim 1 or that is capable of functioning in the manner described in claim 1. Therefore, any obviousness rejection based on Mena would also be improper.

The references cited relative to the dependent claims do not disclose the deficiencies of Mena, as discussed in a prior response. Therefore, no combination of the references results in the claimed invention.

Summarizing, the principal reference, Mena, does not disclose or suggest an implant using retention elements which allow placement of an implant in a longitudinal direction but prevent removal of the implant in the opposite longitudinal direction out of the bone. Particularly, the profile of the threaded elements in Mena is opposite to the retention elements specified in the claims herein. Withdrawal of the rejection and allowance of the application are requested.